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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,154	07/11/2005	Ryuichi Morishita	6235-69895-01	2664

24197 7590 08/24/2007
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EXAMINER	
NOBLE, MARCIA STEPHENS	
ART UNIT	**PAPER NUMBER**
1632	

MAIL DATE	DELIVERY MODE
08/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,154	MORISHITA ET AL.	
	Examiner	Art Unit	
	Marcia S. Noble	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,12,14,15 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6, 12, 14, 15, and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 6, 12, 14, 15, and 18-20 are pending. An amendment was filed on 4/16/2007 that amended claims 1, 6, 13, and 14 and new added claims 16 and 17. A supplemental amendment was filed on 5/4/2007 that canceled claims 1-5, 13, 16, and 17, amended claim 6, and added claims 18-20. Claims 6, 12, 14, 15, and 18-20 are under consideration.

Claim Objections

2. Applicant amended claim 6 to recite "HVJ (hemagglutinating virus of Japan)", thereby clarifying the claims. Claim 1 is now canceled and therefore its objection is moot. Therefore, because pending claim 6 has been clarified, the objection is withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. The rejection of claims 1, 3, 6, and 12-15 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, and 5 of U.S. Patent No. 6,936,594 (of record) in view of Hayashi et al (Gene Therapy 8:1167-1173, 2001, IDS) and Barnes et al (J Lipid Res 28:130-137, 1987), is withdrawn.

Applicants amended the claims to include a step of inducing a cerebral infarction in the subject, which is not present in the method of the patent claims and changes the scope of the instant invention. Therefore, the claims no longer are encompassing the same scope. Therefore, the rejection is withdrawn.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

4. The rejection of claims 1, 3, 6, and 12-15, under 35 U.S.C. 112, first paragraph, as containing new matter in their recitation "free of liposome", is withdrawn.

Applicant removed this recitation and therefore the claims no longer recite the new matter. Therefore, the rejection is withdrawn.

Scope of Enablement Rejection

5. Claims 6, 12, 14, 15, and 18-20 as amended, previously presented, and newly added, stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for reducing the infarction area of an induced cerebral infarction comprising (1) administering by direct administration into the subarachnoid space of an animal model an agent comprising a HVJ-envelope vector comprising an isolated nucleic acid encoding a hepatocyte growth factor (HGF) operably linked to a promoter that drives expression of the nucleic acid encoding a HGF and (2) inducing a cerebral infarction in an animal model, wherein said administration results in a reduction of the infarcted area, does not reasonably provide enablement for a method for reducing an infracted area produced of a natural causes infarction comprising administering an gent comprising and HVJ envelope vector by direct injection into the subarachnoid space of any subject prior to the occurrence of said cerebral infarction wherein the HVJ envelope vector comprises an isolated nucleic acid encoding a HGF protein only enclosed within an HVJ-envelope. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

However, the claims still encompass enablement issues previously made of record (see claim 12 in particular). As stated in the scope of enablement of the office

action, mailed 11/15/2007. The claims are only enabled for direct injection of the agent. However, claim 12 recites that the agent is in the form of a tablet, pill, sugar coated tablet, capsule, gel ointment, syrup, slurry, or suspension. However, tablets, pills, sugar coated tablets, some capsules, ointment are associated with oral or topical administration and are not used in direct injections. Therefore, an artisan would not know how to directly inject a tablet, pill sugar coated tablet, capsule, or ointment into subarachnoid space. Therefore, the instant claims are not enabled for such an embodiment.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3, 6, and 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claims 1 and 6 recite, "a hemagglutinating virus of Japan (HVJ)-envelope vector". It is unclear if the virus is being claimed or the HVJ-envelope vector. Amended claims 1 and 6 also recite, "free of liposome". The metes and bounds of this recitation are unclear because given its broadest interpretation, a liposome is a lipid bilary and therefore it is unclear if the claims requiring free of a lipid bilayer.

Claims 3 and 12-15 depend from claims 1 and 6, which have been deemed indefinite. Therefore, dependent claims 3 and 12-15 are rendered indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 6, 12, 14, 15, and 18-20 as amended, previously presented, and new added, are rejected under 35 U.S.C. 102(b) as being anticipated by Morishita et al (Australian Patent Application No. 200073148, published 4/24/2001 now Patent No. 774990; of record) as evidenced by of Hayashi et al (Gene Therapy 8:1167-1173, 2001, IDS) and Barnes et al (J Lipid Res 28:130-137, 1987).

The instant rejection was made of the grounds that the "HVJ-envelope" of the instant application would not be structurally distinguishable from the "HVJ-liposome" of the Morishita because they both comprise DNA encoding HGF, phosphatidylserine, phosphatidylcholine, and cholesterol and therefore Morishita et al anticipates (p. 11 of Non-Final Rejection, mailed 5/11/06).

Applicant traverses this rejection on the grounds that an HVJ-liposome is different than an HVJ-envelope vector. Applicant asserts (see page 4 of remarks filed

4/16/2007) that fusing HVJ to liposome to results in an average diameter that is 1.3 times greater than an HVJ-particle and cites Dzau et al (PNAS 93:11421-25, 1996).

Applicant's argument and Dzau et al have been fully considered and are not found persuasive. Applicants are arguing limitations that are not claimed. There is no requirement with regard to the average diameter of the particle used. Additionally, the claim uses the open language of "comprising". Thus, the citation of Morishita is found to teach the limitations required by the claims. As Applicant points out, Dzau et al discloses that HVJ-viral particles are 300 nm in diameter (p. 11421, col 1) and that a HVJ-liposome is 400-500 nm in diameter (p. 11421, col 2). Applicant's arguments and evidence from Dzau et al are not found persuasive because this demonstrates the difference between the original viral vector size and the HVJ-liposome fusion, not the difference between an HVJ-liposome and an HVJ-envelope vector as claimed. Again, as previously made of record, the HVJ-liposome of the art and the HVJ-envelope vector of the instant claims structurally comprise the same components and would be indistinguishable from each other and functional as the same as well. Therefore, absent evidence to the contrary the HVJ-liposome of the instant art and the claimed HVJ-envelop vector are the same. Therefore, Applicant's arguments are not found persuasive.

Applicant has also amended the claims to recite the process by which the HVJ-envelope is made (see claims 6 and 18-20). However, this discloses a product made by a particular process is not an active step in the claimed method and only characterizes the agent to be administered. "Products of identical chemical composition can not have

mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705. Therefore, since the end product, the HVJ-envelope vector would be indistinguishable from the HJV-liposome disclosed in the instant art and the process of making the vector is not an active step in the method, the means by which the envelope vector is produced does not have patentable weight. Therefore, the instant art still anticipates the embodiments of the vector required in the claimed process.

Applicant also amended the claims to recite a step of inducing a cerebral infarction. Morishita et al discloses that rats were introduced with the HVJ-liposome comprising human HGF before carotid artery obstruction (p. 34), which causes cerebral infarction. Therefore, Morishita et al anticipates the new method step because they specify the induction of cerebral infarction.

Therefore, because Applicant's arguments and amendments to the claims do not obviate the rejection of record, the rejection is maintained for the amended and previously presented claims and extended to the newly added claims.

8. Claims 6, 12, 14,15 and 18-20 as amended, previously presented, and newly added are rejected under 35 U.S.C. 102(b) as being anticipated by Hayashi et al (Gene Therapy 8:1167-1173, 2001, IDS) as evidenced by Barnes et al (J Lipid Res 28:130-137, 1987).

The instant rejection was made of the grounds that the "HVJ-envelope" of the instant application would not be structurally distinguishable from the "HVJ-liposome" of the Hayashi et al because they both comprise DNA encoding HGF, phosphatidylserine, phosphatidylcholine, and cholesterol and therefore Hyashi et al anticipates (p. 11 of Non-Final Rejection, mailed 5/11/06).

Applicant traverses this rejection on the grounds that an HVJ-liposome is different than an HVJ-envelope vector. Applicant asserts (see page 4 of remarks filed 4/16/2007) that fusing HVJ to liposome to results in an average diameter that is 1.3 times greater than an HVJ-particle and cites Dzau et al (PNAS 93:11421-25, 1996).

Applicant's argument and Dzau et al have been fully considered and are not found persuasive. Applicants are arguing limitations that are not claimed. There is no requirement with regard to the average diameter of the particle used. Additionally, the claim uses the open language of "comprising" As Applicant points out, Dzau et al discloses that HVJ-viral particles are 300 nm in diameter (p. 11421, col 1) and that a HVJ-liposome is 400-500 nm in diameter (p. 11421, col 2). Applicant's arguments and evidence from Dzau et al are not found persuasive because this demonstrates a difference between the original viral vector size and the HVJ-liposome fusion, not the difference between an HVJ-liposome and an HVJ-envelope vector as claimed. Again, as previously made of record, the HVJ-liposome of the art and the HVJ-envelope vector of the instant claims structurally comprise the same components and would be indistinguishable from each other and functional as the same as well. Therefore, absent evidence to the contrary the HVJ-liposome of the instant art and the claimed HVJ-

envelop vector are the same. Therefore, Applicant's arguments are not found persuasive.

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Applicant also amended the claims to recite a step of inducing a cerebral infarction. Hyashi et al discloses that rats were introduced with the HVJ-liposome comprising human HGF before carotid artery obstruction (p. 1168, col 1), which causes cerebral infarction. Therefore, Hyashi et al anticipates the new method step because they specify the induction of cerebral infarction.

Therefore, because Applicant's arguments and amendments to the claims do not obviate the rejection of record, the rejection is maintained for the amended and previously presented claims and extended to the newly added claims.

9. Claims 6, 12, 14, 15, and 18-10 as amended, previously presented, and newly added are rejected under 35 U.S.C. 102(e) as being anticipated by Morishita et al (US

Pat No. 6,936,594) as evidenced by of Hayashi et al (Gene Therapy 8:1167-1173, 2001, IDS) and Barnes et al (J Lipid Res 28:130-137, 1987).

Applicant traverses this rejection on the grounds that an HVJ-liposome is different than an HVJ-envelop vector. Applicant asserts (see page 4 of remarks filed 4/16/2007) that fusing HVJ to liposome to results in an average diameter that is 1.3 times greater than an HVJ-particle and cites Dzau et al (PNAS 93:11421-25, 1996).

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Applicant has also amended the claims to recite the process by which the HVJ-envelope is made (see claims 6 and 18-20). However, this discloses a product made by a particular process, not an active step in the claimed method and this only characterizes the agent to be administered. Therefore, since the end product, the HVJ-envelop vector would be indistinguishable from the HJV-liposome disclosed in the instant art and the process of making the vector is not an active step in the method, the means by which the envelope vector does not have patentable weight. Therefore, the instant art still anticipates the embodiments of the vector required for the claimed process.

Applicant also amended the claims to recite a step of inducing a cerebral infarction. Morishita et al discloses that rats were introduced with the HVJ-liposome comprising human HGF before carotid artery obstruction (p. 34), which causes cerebral infarction. Therefore, Morishita et al anticipate the new method step because they specify the induction of cerebral infarction.

Therefore, because Applicant's arguments and amendments to the claims do not obviate the rejection of record, the rejection is maintained for the amended and previously presented claims and extended to the newly added claims.

10. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571)-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcia S. Noble

/Thaian N. Ton/
Primary Examiner
Art Unit 1632